REMARKS

Upon entry of the present Amendment, claims 45-49, 53, 56, 58-62, 66, 69-74, 81, 84, 86-95, 99 and 102-110 will be pending. Claims 1-44, 50-52, 54, 55, 57, 63-65, 67, 68, 75-80, 82, 83, 85, 96-98, 100 and 101 are withdrawn from consideration and/or canceled. Applicant reserves the rights to pursue the withdrawn and/or canceled subject matter in a subsequent application. Support for amended claims 45 and 70 for reciting "said gp55 antigen binds to an antibody produced by the hybridoma cell line CCTCC-C200305, said gp95 antigen binds to an antibody produced by the hybridoma cell line CCTCC-C200306, and said gp210 antigen binds to an antibody produced by the hybridoma cell line CCTCC-C200307, respectively" can be found throughout the application and, *inter alia*, in Example 2 at page 24, line 19 through page 26, line 9 of the present specification. Claims 46-49, 56, 58, 66, 69, 74, 87, 89 and 99 are amended to conform with the amendments of claims 45 and 70 and/or for other formality reasons. The above-described amendments do not introduce any new matter into the present application.

Rejections under 35 U.S.C. § 112

Written description

Claims 45-49, 53, 56-62, 66, 69-74, 79, 81, 84-95, 99 and 102-110 stand rejected under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the Examiner asserted that the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed immunogenic composition comprising an antibody with one or more antigen binding sites for one or more gp55, gp95, gp115 or gp210 antigens on the surface of one or more target hepatocellular carcinoma cells, lymphoma cells, colon carcinoma cells or gastric cancer cells and the method of preparing the said composition.

In the interests of advancing prosecution of the present application and without accepting the Examiner's assertion, applicant has amended the two independent claims, 45 and 70, to recite "said gp55 antigen binds to an antibody produced by the hybridoma cell line CCTCC-C200305, said gp95 antigen binds to an antibody produced by the hybridoma cell line CCTCC-C200306, and said gp210 antigen binds to an antibody produced by the hybridoma cell line CCTCC-C200307, respectively." It is respectfully submitted that the written description rejection is rendered moot by the above amendments (*See Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 296 F.3d 1316, 63 U.S.P.Q.2D (BNA) 1609 (Fed. Cir. 2002) holding that in light of the history of biological deposits for patent purposes, the goals of the patent law, and the practical difficulties of describing unique biological materials in a written description, reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112, ¶ 1).

Enablement

Claims 45-49, 53, 56-62, 66, 69-74, 79, 81, 84-95, 99 and 102-110 stand rejected under 35 U .S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In particular, the Examiner asserted that the specification does not disclose how to make and/or use the instant invention. The Examiner stated that the claimed method of making a composition and the said composition comprising one or more hepatocellular carcinoma, lymphoma or colon carcinoma or gastric cancer cells and one or more antibodies comprising one or more binding sites for one or more gp55, gp95, gp115 or gp210 antigens on the surface of one or more of the autologous target cells encompasses: (1) making and using antibodies to any 55, 95, 115 or 210 kDa glycoprotein, *i.e.*, "gp55", "gp95", "gp115" or "gp210" on the surface of any isolated autologous target hepatocellular carcinoma, lymphoma, colon or gastric carcinoma cell.

The Examiner alleged that the specification has not enabled the breadth of the claimed invention in view of the teachings of the specification because the claims encompass a composition which comprises an antibody with a specificity against any cell surface protein on any of the said target cells recited in the instant claims. The Examiner also alleged that the state of the art is such that it is unpredictable in the absence of appropriate evidence whether the claimed compositions can be made and/or used. However, the Examiner stated that the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the hybridoma producing the said antibody.

In the interests of advancing prosecution of the present application and without accepting the Examiner's assertion, applicant has amended the two independent claims, 45 and 70, to recite "said gp55 antigen binds to an antibody produced by the hybridoma cell line CCTCC-C200305, said gp95 antigen binds to an antibody produced by the hybridoma cell line CCTCC-C200306, and said gp210 antigen binds to an antibody produced by the hybridoma cell line CCTCC-C200307, respectively." It is respectfully submitted that the enablement rejection is rendered moot by the above amendments.

Indefiniteness

Claims 45-49, 53, 56-62, 66, 69-74, 79, 81, 84-95, 99 and 102-110 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner alleged that claims 45, 58, 65-68, 70, 87, 89, 98-101 are indefinite in the recitation of "gp55, gp95, gp115 or gp120 [gp210]" antigens or antibodies comprising binding sites to the said "gp55, gp95, gp115 or gp120 [gp210]" antigens because the characteristics of the said gp55, gp95, gp115 and gp210 antigens and hence, that of the said antibodies, are not known.

It is respectfully submitted that this rejection is rendered moot by the amendments of claims 45 and 70.

The Examiner also made the following rejections:

a. Claims 46-49 and 58 recite the limitation "said one or more hepatocellular carcinoma cells." There is allegedly insufficient antecedent basis for this limitation in the claims.

b. Claim 56 recites the limitation "one or more". There is allegedly insufficient antecedent basis for this limitation in the claim.

c. Claim 45 is allegedly indefinite in the recitation of "a bispecific monoclonal antibodies" because it is allegedly not clear what is meant.

d. Claim 66 recites the limitation "one or more gp55...". There is allegedly insufficient antecedent basis for this limitation in the claim.

e. Claims 66 and 99 are indefinite in the recitation of "antigen comprises gp95 antigens because it is allegedly not clear what is meant.

It is respectfully submitted that these rejections are rendered moot by the amendments of claims 45-49, 56, 58, 66 and 99.

It is respectfully submitted that the rejection of claims 45-49, 53, 56-62, 66, 69-74, 79, 81, 84-95, 99 and 102-110 under 35 U.S.C. § 112 is overcome by the above remarks and/or amendments and must be withdrawn.

Provisional double patenting

Claims 70-74, 79, 81, 84-95, 99 and 102-110 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 103-139 of copending Application No. 08/872,527.

Applicant notes the provisional nature of the double patenting rejection. Applicant will submit a terminal disclaimer once allowable subject matter is indicated in the present application.

CONCLUSION

Applicant submits that the rejections of claims 45-49, 53, 56-62, 66, 69-74, 79, 81, 84-95, 99 and 102-110 under 35 U.S.C. § 112 have been overcome by the above remarks and/or

amendments. Early allowance of the pending claims 45-49, 53, 56-62, 66, 69-74, 79, 81, 84-95, 99 and 102-110 are earnestly requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant(s) petition(s) for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 532732000201.

Respectfully submitted,

Dated: June 11, 2003 By: _____

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